IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: SERZONE
PRODUCTS LIABILITY LITIGATION

MDL NO. 1477

THIS DOCUMENT RELATES TO ALL CASES

ORDER

Rule 23 of the Federal Rules of Civil Procedure requires this court to direct Bristol-Myers to provide class members with the best notice practicable of the proposed settlement. The Supreme Court has concluded that the best notice practicable in class action cases is individual notice. *Eisen v. Jacquelin*, 417 U.S. 156, 177 (1974). In this case, Bristol-Myers could best achieve such individual notice by using the information contained in its adverse event report (AER) database. This database identifies a large number of class members who are most likely entitled to some recovery under the terms of the settlement agreement. The identifying information in the AERs, however, is protected by federal privacy regulations. I **ORDER** the defendant to provide individual notice to all class members who are reasonably identifiable, namely the plaintiffs and individuals who are the subject of a Serzone-related AER. To reconcile the countervailing interest in protecting individual privacy with the interest in providing potential plaintiffs with the best notice practicable, the court **DIRECTS** the defendant to effectuate this order as follows:

a) Bristol-Myers shall mail individual notice directly to all individuals identified in its AER database as having experienced an adverse event related to Serzone, assuming the individual's mailing address is available. Envelopes shall be marked "Personal and Confidential" and bear

no notation that the proposed class action settlement involves Serzone or a psychotherapeutic drug. The mailing shall contain only the judicially-approved individual notice. There shall be no reference to any identifying information from the AER other than the Serzone user's name and address on the outside envelope. Additionally, there shall be no reference to the existence of an AER.

b) Bristol-Myers shall mail copies of all judicially-approved forms of notice, including both the individual notice and the summary notice, directly to any healthcare professional who submitted an AER. The mailings shall also contain a letter informing the physicians that the enclosed notice is merely intended to alert them of the pending settlement and to encourage them to use their discretion to notify any patient who took Serzone of the pending settlement.

I **FIND** that the mailing of individual notice is a communication necessary to the conduct of this judicial proceeding and that the directives in this order preserve the intent of the FDA's privacy regulations.

I. Background

Upon review of the settlement agreement reached by the plaintiffs and the defendant Bristol-Myers in the actions consolidated in this multidistrict litigation, the court entered an order preliminarily approving the settlement agreement and conditionally certifying the settlement class [Docket 170]. In that order, the court approved the proposed forms of notice, which explain the terms of the settlement agreement. Distribution of the notice incorporates various media vehicles, the internet, and individual mailings to class members. Rule 23(c)(2) of the Federal Rules of Civil Procedure informs courts of the notice required in the type of class action involved in the instant case:

> For any class certified under Rule 23(b)(3),[1] the court must direct to

[1]All members of a class certified under Rule 23(b)(3) are part of the class unless they opt out. Therefore, notice is of utmost importance because a class member who fails to opt out is

> class members the best notice practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort.

Fed. R. Civ. Pro. 23(c)(2)(B).

Unquestionably, class members who are currently named plaintiffs in the underlying multidistrict litigation must receive individual notice as they are easily identifiable through reasonable effort. A more complex question is presented, however, by those class members known to Bristol-Myers only through its database of adverse event reports. Although these individuals are identifiable through a reasonable effort, the information that identifies them in the AERs is protected by federal privacy regulations. 21 C.F.R. § 20.63(f)(2004). These privacy regulations are designed to encourage patients and health care professionals to voluntarily report adverse events to drug manufacturers. *Id.*; 21 C.F.R. § 314.80.

The Food and Drug Administration (FDA) requires drug manufacturers to maintain reports of expected and unexpected adverse reactions to their products. 21 U.S.C. § 355(k)(1). The FDA uses this information to monitor the safety of prescription drugs and medical devices. 21 C.F.R. § 314.80. According to the FDA, "the receipt of postmarket reports of adverse events associated with a regulated product is critical to the agency's ability to help protect the public health." *Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules*, 59 Fed. Reg. 3944 (Jan. 27, 1994). Despite the importance of such adverse event reports, the FDA relies on patients and health professionals to voluntarily report such events. Many individuals are reluctant to come forward with such information for fear of reprisal. For example, healthcare professionals may be reluctant to report such events because they fear subsequent, third-party litigation. Anonymity, however, promotes honest

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bound by the terms of the settlement agreement or outcome of the class litigation. 7B CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1786 (2d ed. 2004).

reporting. Accordingly, the FDA enacted 21 C.F.R. § 20.63(f) to help ensure the privacy of voluntary reporters and to encourage such reporting. Section 20.63(f) provides in part:

> The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the names, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report.

The exceptions to § 20.63(f) allow for the disclosure of individuals' identities in three limited circumstances: (1) when both the voluntary reporter and the person who experienced the adverse event consent in writing to disclosure; (2) when both parties are involved in medical malpractice litigation, and the court orders disclosure of their identities; or (3) when the person who experienced the adverse event requests the report, in which case the identities of any other individuals are still excluded from the report. *Id.*

II. Analysis

In allowing the defendant to provide notice directly to the individuals identified in its AER database, I do not rely on any of the exceptions to the privacy requirements listed above. Instead, I rely on the finding that the confidentiality secured by the regulation is not absolute. As noted by the Eighth Circuit, the protection provided by § 20.63(f) is not the equivalent of a new physician-patient privilege. *In re Medtronic*, 184 F.3d 807, 811 (8th Cir. 1999). The confidentiality provided by § 20.63(f) is subject to certain qualifications.

One such qualification, upon which I rest my decision today, is the use of the word "disclosure" in the regulatory language of § 20.63(f). To "disclose" is commonly defined as "to expose to view: reveal" or "to make known: divulge." WEBSTER'S II NEW COLLEGE DICTIONARY 324 (1995). I find

that the disclosure prohibited by § 20.63(f) refers to "public disclosure." *See* 21 C.F.R. § 20.28 ("A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for *public disclosure* shall be made only in the form of a regulation published or cross-referenced in this part.")(emphasis added). Section 20.63 is found in the exemptions subpart of Part 20, which is entitled "Public Information." 21 C.F.R. § 20.63. Moreover, § 20.63(a) specifically refers to "public disclosure." *Id.* I find that the directives of this order do not provide for any prohibited public disclosure of the identifying information in the AERs. Using the information currently in its possession, Bristol-Myers can directly contact the individuals identified in its AER database. Such direct contact eliminates the unnecessary involvement of others, such as attorneys or claims administrators, in sending the notices. Since Bristol-Myers is already in possession of the AERs, the process of sending the notices involves no disclosure to any third party.

I find such direct contact to be especially appropriate given the sensitive nature of this case. As the Second Circuit has noted, "there are few matters that are quite so personal as the status of one's health." *Doe v. City of New York*, 15 F.3d 264, 267 (2d Cir. 1994). Furthermore, Serzone is a psychotherapeutic drug, and the subject of mental health is arguably more personal than that of physical health.

In turn, I must examine whether the receipt of such notice would violate the privacy of the individuals named in the AERs. In those instances where the patient who is the subject of the adverse report is also the voluntary reporter, Bristol-Myers may mail the notice directly to the individual without any worry of disclosure. The person being contacted is also the original supplier of the information, and therefore, no information is being revealed or disclosed. Moreover, the person being contacted already knows of the existence of the report.

Because both healthcare practitioners and patients can voluntarily submit AERs, the voluntary

reporter and the patient who experienced the adverse event is often not the same person. *Adcox v. Medtronic, Inc.* 131 F. Supp. 2d 1070, 1072 (E.D. Ark. 1999). In fact, healthcare professionals comprise a significant majority of voluntary reporters. In some cases, a doctor may inform the patient when he submits an AER regarding the patient. If Bristol-Myers mails the notice directly to patients who know their doctors submitted an AER about their condition, there is no disclosure of information protected by § 20.63(f). In other cases, however, a patient may not know that his or her doctor submitted such a report. It is possible that mailing the notice directly to the patient who is the subject of the report may operate to reveal the existence of an AER to the patient.

I find, however, that the receipt of such notice by patients unaware of the existence of the AERs does not constitute the type of disclosure prohibited by the federal privacy regulations. Section 20.63 protects the identifying information in the report, not the existence of the report itself. 21 C.F.R. 20.63(f). Additionally, the mailing will not contain a reference to the AERs. Thus, I find it highly unlikely that an individual who receives the notice will make the logical leap that an AER exists. The identity of the healthcare professional who submitted the AER need not be revealed in order for Bristol-Myers to send notice to the patient identified therein, and the mailing will contain no identifying information other than the Serzone user's name and address on the outside envelope. Thus, the notice directed by this order will not reveal or divulge any identifying information in the AER.[2]

To further ensure that the best notice practicable is achieved, I direct Bristol-Myers to mail copies of the individual and summary notice forms directly to all healthcare professionals who submitted a Serzone AER. In some circumstances, the address of the patient who experienced the

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[2]I cannot maintain that a patient who is able to discover the existence of an AER regarding his condition may not be able to surmise or guess the identity of the voluntary reporter, but such speculation is outside the scope of protection of § 20.63(f). Even if the patient requests to see the report pursuant to § 20.63(f)(1)(iii), the exception still requires all identifying information other than that pertaining to the patient to be redacted from the report.

adverse event may be missing from the AER or the patient's address may no longer be current. For those AERs that omit patient information, the healthcare professional who submitted the report may be in the best position to contact the patient.

However, I leave the ultimate decision of whether to provide patients with notice of the Serzone settlement to the discretion of the reporting healthcare professional. I recognize that health care professionals may not welcome receipt of the notices in light of potential administrative inconveniences. I also find that it would violate the provisions of § 20.63(f) to require the reporting healthcare professional to notify their patients that they had previously submitted an AER concerning the patients' reaction to Serzone. Such an order would essentially be the equivalent of an order to reveal the identity of the voluntary reporter to the patient.

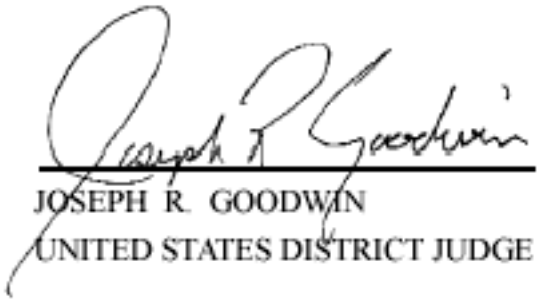
Accordingly, a letter shall accompany the notice provided to physicians. This letter will inform physicians that they are not required to notify any patients of the settlement, nor are they required to distribute the notices. In ordering Bristol-Myers to provide notice to the reporting healthcare professionals, the court merely seeks to alert the physicians to the existence of the Serzone litigation and pending settlement. Nevertheless, all reporting health care professionals are strongly encouraged to communicate the news of the settlement to patients who used Serzone. Their cooperation will help ensure that all class members receive notice of the pending settlement.

I find the mailing of individual notice to be a communication necessary to the conduct of this judicial proceeding. Rule 23(d) of the Federal Rules of Civil Procedure empowers courts to enter appropriate orders in the handling of class actions and particularly authorizes such orders with regard to notice. Pursuant to this grant of authority, I **ORDER** Bristol-Myers to provide individual notice in the manner and form set forth above. Furthermore, I **ORDER** that no identifying information from the AERs may be revealed to any of the MDL plaintiffs or their counsel, to any third party, or to any public

record. I **FIND** that the directives established herein are consistent with the intent of the FDA's privacy regulation and do not disrupt the underlying goals of § 20.63. The FDA's intent in enacting the regulation was to encourage the voluntary reporting of adverse events from products in the market to help achieve the goal of improving the quality and safety of prescription drugs and medical devices. Through this order, the court seeks to ensure that those individuals who have suffered adverse events are aware of their options in seeking a remedy.

The court **DIRECTS** the Clerk to send a copy of this Order to Defendant's Liaison Counsel and Plaintiffs' Liaison Counsel, and **DIRECTS** the Clerk to post this published opinion at http://www.wvsd.uscourts.gov.

ENTER: December 21, 2004



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE